

**THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION
CIVIL CASE NO. 1:12-cv-00311-MR-DLH**

**ROBIN L. HARRIS, Individually and)
as Executrix of the Estate of Billy)
David Harris, deceased,)
)
Plaintiffs,)
)
vs.)
)
AJAX BOILER, INC., et al.,)
)
Defendants.)
_____)**

ORDER

THIS MATTER is before the Court on Duke University Health System, Inc.'s Motion for Protective Order and Motion to Set Aside or for Reconsideration of Order Governing Release of Pathology Materials [Doc. 126]. The Court held a hearing on this motion on February 24, 2014.

I. FACTUAL AND PROCEDURAL BACKGROUND

On October 1, 2012, Billy David Harris and his wife, Robin L. Harris, filed a Complaint alleging that Mr. Harris developed mesothelioma as a result of breathing asbestos that had been contained in products and/or equipment of the Defendants sued. [Doc. 1]. Mr. Harris died on January 12, 2013, and Robin Harris thereafter filed motions to substitute herself as Plaintiff, as Executor of the Estate of her deceased husband, and for leave

to file the First Amended Complaint containing a cause of action for wrongful death. [Docs. 69, 70]. After these motions were granted [see Doc. 77], the Plaintiff filed the First Amended Complaint [Doc. 78].

Before Mr. Harris died, tissue samples (“pathology materials”) were obtained from different locations in his lungs and lymph nodes by doctors at Duke University Health System, Inc. (“Duke”). Such pathology materials, usually consisting of tissue slides or tissue blocks, can assist treating physicians and pathologists retained by parties in asbestos cases in forming opinions about the nature of the purported disease and its causes. There were 22 blocks of biopsy tissues obtained from Mr. Harris, and each is anatomically different.

On May 8, 2013, in response to a written request for pathology materials, Duke provided a total of 156 pathology slides, including 12 unstained recut pathology slides from tissue blocks SF-11-422266, A1-3, and D1-10, to Plaintiff’s counsel. On June 13, 2013, a replacement pathology slide for one recut pathology slide was sent to Plaintiff’s counsel. These slides were shared with Defendants’ counsel.

On November 26, 2013, Duke provided one set of recut pathology slides, including one slide from SL-11-38785 and 18 slides from SF-11-

422266, to Steve Williamson, counsel for the Defendant Cleaver-Brooks, Inc. for testing by all of the Defendants.¹

After receiving the tissue slides on October 7, 2013, Mr. Williamson's paralegal/nurse sent them to Defendants' expert, Dr. Tim Oury, on October 10. After examining the slides, Dr. Oury informed the Defendants that analysis of some additional tissue blocks would be necessary for more specific findings. The Defendants therefore contacted the Duke pathology lab to request additional tissue. In response, the Defendants were advised that it was Duke's policy not to release original materials but that recut sections were available. Therefore, the Defendants agreed to receive re-

¹In their response to Duke's motion, the Defendants explain that it is customary in asbestos cases for only one defense attorney to take lead responsibility for obtaining documents and materials that can be used by most or all defense attorneys, such as medical records and pathology materials. In this case, Mr. Williamson agreed to be "liaison counsel" and to obtain the pathology materials for all defendants in this case, which is why Mr. Williamson filed the motion with this Court seeking an entry of an order for the release of pathology materials [Doc. 121] instead of each defendant filing a separate motion. After the motion was filed, however, counsel for Duke asserted that it was improper for Mr. Williamson to litigate the issue of the pathology materials in the possession of Duke because another attorney within his firm (not involved in the present lawsuit or in the asbestos litigation) was representing Duke on an entirely different and unrelated matter, and Duke's counsel intimated that there was a conflict of interest and that Mr. Williamson should cease to be involved in the current dispute involving pathology materials. In light of these concerns, other defense counsel have agreed to take over Mr. Williamson's efforts to obtain pathology material on behalf of all defendants in this case.

cut slides from two specifically-identified tissue blocks, which the Defendants received on November 27, 2013.

After Dr. Oury had the opportunity to review the recut tissue slides, he concluded that he still needed certain specific tissue blocks to examine and to undertake a digestion analysis, and that he could not do such an analysis with the previously provided pathology materials. Accordingly, the Defendants again requested original tissue blocks (specifically, SF11042266, blocks F1 and G1) from Duke. In response, the Defendants were again advised that it was Duke's policy not to release original tissue blocks.

On December 12, 2013, the Defendants filed a motion seeking the entry of an order authorizing the release of Mr. Harris's pathology materials from Duke.² The Plaintiff did not oppose the Defendant's motion. In an Order entered December 31, 2013 ("Pathology Order"), the Court granted the Defendants' motion.³ [Doc. 122]. On January 8, 2014, Duke filed the

² The Defendants directed their motion to "Duke University Medical Center Department of Pathology." The correct entity, however, is Duke University Health System, Inc.

³ Notably, the Defendant's motion did not describe the specific nature of the pathology materials requested (*i.e.*, original tissue blocks) or the basis of Duke's objection to the release of such material. Further, the Defendant's motion fails to mention that previous pathology material had been provided by Duke, thereby creating the impression for the Court that the Defendants had not received *any* pathology materials from Duke prior to filing the motion.

present motion, moving for a protective order to set aside and/or for reconsideration of the Pathology Order.

II. DISCUSSION

Duke moves for a protective order pursuant to Rule 26 of the Federal Rules of Civil Procedure, arguing that the Defendants' request for pathology materials is overly broad and unduly burdensome.⁴ See Fed. R. Civ. P. 26(c)(1) (providing that a party or any person from whom discovery is sought may move for a protective order, and the court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense). Specifically, Duke moves for a protective order on the grounds that it already has provided pathology materials to the Defendants or for the Defendants' benefit on two occasions prior to the entry of the Order. Duke further moves for a protective order on the grounds that it is mandated by Clinical Laboratory Improvement Amendments (CLIA) and the College of American

⁴ In its motion, Duke further objected to the Pathology Order on the grounds that, as a non-party, it was not served with a subpoena or "any other lawful process" prior to the Order being entered and thus was deprived of any notice and an opportunity to be heard before being ordered to comply. [Doc. 127 at 7-9]. Duke, however, appeared to abandon this argument in its reply brief [see Doc. 130 at 5] and did not assert such argument during the motion hearing. Accordingly, the Court need not address these arguments further.

Pathologists (CAP), both of which govern the certification and accreditation of clinical laboratories, to retain original pathology for specified periods of time and therefore it cannot comply with the Pathology Order without violating these requirements.

As an initial matter, Duke's argument that it is entitled to a protective order because it has already provided pathology samples to the Defendants is simply without merit. The Defendants have shown that the materials previously provided by Duke were not sufficient for Dr. Oury to complete the kind of testing that the Defendants require. The Defendants' request for further pathology materials, therefore, is reasonable, and the fact that Duke has already provided some pathology samples does not insulate it from complying with the Defendants' additional request or otherwise entitle it to a protective order.

More importantly, contrary to Duke's central argument, the Clinical Laboratory Improvement Amendments (CLIA) requirements do not prevent this Court from ordering the release of tissue blocks or sections of tissue blocks. CMS (The Centers for Medicare & Medicaid) implements the CLIA program, which is based on regulations found in 42 Code of Federal Regulations (CFR) Part 493. www.ncdhhs.gov/dhsr/ahc/clia/ (last visited

Apr. 1, 2014).⁵ The CLIA requirements establish quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient tests. Id.

Pursuant to the federal regulations, CMS may impose sanctions on any facility that is out of compliance with one or more CLIA requirements, including suspension, limitation, or revocation of any type of CLIA certificate. See 42 C.F.R. § 493.1806. Duke, however, will not be subject to any such sanctions by complying with this Court's Order. First, the CLIA requirements provide that a laboratory "[r]etain pathology specimen blocks for at least 2 years from the date of examination." 42 C.F.R. § 493.1105(a)(7)(ii). The tissue blocks at issue were obtained from Mr. Harris more than two years ago, and thus the CLIA regulations do not require Duke to retain those tissue blocks. Additionally, a laboratory must "[p]reserve remnants of tissue for pathology examination until a diagnosis is made on the specimen." 42 C.F.R. § 493.1105(a)(7)(iii). As alleged in Plaintiff's Amended Complaint, however, a diagnosis has already been made regarding Mr. Harris's disease. [See Doc. 76 at ¶7]. Therefore,

⁵ A copy of this web page is attached to this Order as Exhibit 1.

releasing the tissue blocks that are the subject of the Court's Order will not violate this provision of the CLIA regulations.

Duke also cites the College of American Pathologists (CAP) guidelines, which require an accredited laboratory to retain surgical pathology specimens for a specified period of time. The CAP guidelines, however, are entirely voluntary. See College of American Pathologists, Professional Relations Manual at 3 (12th ed. 2003) (hereinafter "CAP Manual") ("the College of American Pathologists strives to provide the pathologist with *voluntary* guidelines for professional practices") (emphasis added).⁶ While the CAP Manual provides that surgical pathology slides and paraffin blocks should be retained for a period of 10 years, they are recommendations and do not have the force of law. See id. at 127 ("The College of American Pathologists makes the following recommendations for the minimum requirements for the retention of laboratory records and materials. They meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 . . .").

Furthermore, CAP has procedures for accredited laboratories to follow when requests are made to those laboratories for the release of

⁶ A copy of the CAP Manual was filed in the record as an exhibit to the Defendants' Response. [Doc. 128-2].

pathology materials. As part of those procedures, CAP expressly recognizes a court's ability and authority to order the release of pathology materials:

Attorney Requests for Pathology Reports and Slides

1. If a written request for pathology reports and slides is received from an attorney, the pathology department will first respond by sending the standard letter requesting (a) the reason for the request and (b) the specific case accession number requested, and (c) stating the policy that only recuts of slides may be sent. . . .

. . . .

5. Original slides will be submitted ONLY if a court so orders, in which case *there is no alternative but to comply*. However, if the original material is subsequently broken or lost, the pathology group will be operating under the protection of the court.

Id. at 130 (emphasis added). This provision of the CAP Manual makes clear that Duke is not at risk of losing its accreditation by complying with this Court's Order, since Duke "will be operating under the protection of the court." Id.

The CAP Manual also discusses at length what a laboratory should do when surgical pathology materials are requested by a physician, another institution, or an attorney (although it is assumed in this discussion that an attorney making such a request would be contemplating filing a malpractice claim against the healthcare provider housing the laboratory).

The CAP Manual first notes that “[w]hen the pathologist is responding to a request for review of patient slides or other patient materials, it is preferable to obtain consent from the patient permitting release of these materials.” Id. at 6. Here, the Defendants have obtained the Plaintiff’s written permission for the release of pathology materials and such written authorization was provided to Duke. The Manual also observes that “it is *advisable* to send recuts -- rather than original slides -- if the pathologist determines that recuts are comparable to the original materials.” Id. (emphasis added). The use of the term “advisable” clearly implies that the laboratory may send original slides. The Manual further explains that “retaining original materials is important *if a malpractice case is brought.*” Id. The present action, however, is not a malpractice case, and neither Duke nor any of its doctors are parties to this action. Further, the Manual notes that retaining the original pathology material “will avoid the awkward situation that can arise if the originals have been furnished in response to a request from a plaintiff’s attorney, and then a similar request is received from an attorney for a defendant clinician.” Id. This concern is clearly not implicated here, as all of the parties to the litigation are in agreement that the Defendants should be entitled to the original tissue samples.

The CAP Manual goes on to say that “[i]f the court orders the release of the original materials, the pathologist will then be under the protection of the court, should these materials be lost or destroyed.” Id. Again, this language makes it abundantly clear that CAP recognizes that courts have the authority to compel the release of original pathology materials, even if there will be destructive testing.

For all of these reasons, the Court concludes that the CLIA and CAP requirements do not prevent Duke from complying with the Court’s Order.

Finally, the Court notes that in bringing this motion, Duke challenges the manner in which it was directed to produce the pathology samples in this case (*i.e.*, a court order as opposed to a Rule 45 subpoena). The Court, however, does not find that Duke suffered any prejudice by the procedure utilized by the Court; in fact, Duke was probably afforded more protection by the method followed by the Defendants in seeking a court order rather than the usual method of defense counsel themselves issuing a subpoena without any intervention of or consideration by the Court. Once the Pathology Order was entered, Duke was able to file its motions and present its arguments against production, and therefore was afforded the same opportunity it would have had if a subpoena for the pathology materials had been served and Duke sought protection from complying with

the subpoena. While the Court does not find that Duke suffered any prejudice in the instant case, the Court encourages the parties to utilize the Rule 45 procedures for any further pathology material requests. Utilization of the subpoena process will allow the parties to resolve or at least minimize any disputes regarding the scope of the production prior to seeking the involvement of the Court.

III. CONCLUSION

In sum, the Court concludes that Duke's Motion for Protective Order must be denied. The Court specifically finds that the Pathology Order directing Duke to release to defense counsel pathology materials of Mr. Harris will not detrimentally affect Duke's accreditation; it does not require Duke to violate any law or legally-enforceable regulation; and the Order is not oppressive or unduly burdensome. The Court further finds that if the requested materials were not produced, the Defendants would be unduly prejudiced in defending the Plaintiff's claims.

ORDER

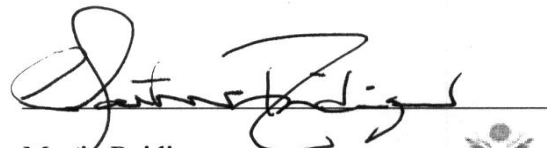
IT IS, THEREFORE, ORDERED that Duke University Health System, Inc.'s Motion for Protective Order and Motion to Set Aside or for Reconsideration of Order Governing Release of Pathology Materials [Doc.

126] is **DENIED**. Duke University Health System, Inc. shall make available the pathology material requested (specifically, SF11042266, blocks F1 and G1) to the Defendants' expert, Dr. Tim Oury, within ten (10) days of the entry of this Order.

IT IS FURTHER ORDERED that upon completion of the desired testing, the Defendants shall have their expert return any unused material, to the extent such material remains, to Duke University Health System, Inc.

IT IS SO ORDERED.

Signed: April 7, 2014


Martin Reidinger
United States District Judge

